

EXHIBIT 4

Confidential - Subject to Stipulation and Order of Confidentiality

1 - - -
2 :SUPERIOR COURT OF
:NEW JERSEY
3 IN RE: :LAW DIVISION -
PELVIC MESH/GYNECARE :ATLANTIC COUNTY
4 LITIGATION :
:MASTER CASE 6341-10
5 :
:CASE NO. 291 CT

6 - - -
CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
7 CONFIDENTIALITY
- - -

8
September 18, 2012
9 VOLUME III
10 - - -

11 Transcript of the continued
12 deposition of PIET HINOUL, M.D., Ph.D., called for
13 Videotaped Examination in the above-captioned
14 matter, said deposition taken pursuant to Superior
15 Court Rules of Practice and Procedure by and before
16 Ann Marie Mitchell, a Federally Approved Certified
17 Realtime Reporter, Registered Diplomate Reporter,
18 Certified Court Reporter, and Notary Public for the
19 State of New Jersey, at the offices of Riker Danzig
20 Scherer Hyland & Perretti LLP, Headquarters Plaza,
21 One Speedwell Avenue, Morristown, New Jersey,
22 commencing at 10:16 a.m.

23 - - -
GOLKOW TECHNOLOGIES, INC.
24 877.370.3377 ph|917.951.5672 fax
deps@golkow.com
25

Confidential - Subject to Stipulation and Order of Confidentiality

1 (Deposition Exhibit No.
2 Plaintiff's-884, Article entitled
3 "Transvaginal mesh repair of anterior and
4 posterior vaginal wall prolapse: A
5 clinical and ultrasonographic study," 7
6 pages, was marked for identification.)

7 - - -

8 BY MR. SLATER:

9 Q. -- an article that I think may have
10 been marked at a previous deposition as 759, but I
11 don't have the marked copy, so we're just going to
12 remark it 884.

13 The article we've now marked as

14 Exhibit 884 is an article you're certainly familiar
15 with. Correct?

16 A. Correct.

17 Q. In fact, there's an acknowledgment at
18 the end of the article, "We are very grateful to Dr
19 Piet Hinoul for his contribution when reviewing this
20 paper."

21 Do you see that?

22 A. Yep.

23 Q. Wouldn't it have been nice if
24 Dr. Altman had had an acknowledgment in the article
25 he published in the New England Journal of Medicine

Confidential - Subject to Stipulation and Order of Confidentiality

1 where he said, we are very grateful to Dr. Piet
2 Hinoul, Dr. Aaron Kirkemo, Dr. David Robinson and
3 Judith Gauld for their contribution when reviewing
4 this paper? Wouldn't that have been a good thing
5 for him to say?

6 MR. SNELL: Objection to form.

7 THE WITNESS: My mother would have
8 been proud of me in the New England Journal, but
9 have you seen the revisions I've made to this paper
10 as opposed to a couple of suggestions I made freely
11 to Dr. Altman?

12 BY MR. SLATER:

13 Q. Wouldn't it have been nice if

14 Dr. Altman had actually acknowledged you and the
15 others at Ethicon having made whatever contributions
16 you made to his article?

17 MR. SNELL: Objection to form.

18 THE WITNESS: I don't think it was
19 necessary.

20 BY MR. SLATER:

21 Q. It would have been a better practice
22 if Dr. Altman had disclosed your involvement and the
23 involvement of the others in Ethicon. That would
24 have been the better way to do things, right, rather
25 than affirmatively saying that nobody had any

Confidential - Subject to Stipulation and Order of Confidentiality

1 involvement?

2 MR. SNELL: Objection, form.

3 THE WITNESS: No. They disclose
4 Ethicon, and I don't think we had a substantial
5 impact on the paper.

6 BY MR. SLATER:

7 Q. They disclosed that Ethicon gave
8 money to help fund the study. Correct?

9 A. Correct.

10 Q. That tells nobody that anybody at
11 Ethicon looked at the manuscript when it was in
12 draft, made comments and edits to the manuscript.
13 Correct?

14 MR. SNELL: Objection, form.

15 THE WITNESS: We didn't make edits.

16 BY MR. SLATER:

17 Q. You did make edits, though. There
18 were deletions that were shown, and then it was up
19 to Altman and his co-authors whether they accepted
20 those. Correct?

21 A. Suggestions for editing, yes. Much
22 different from this paper. I don't know where
23 you've got my e-mail on this and how much red there
24 was on this paper.

25 Q. Oh, I read it all. It's sitting

Confidential - Subject to Stipulation and Order of Confidentiality

1 right here.

2 A. Okay. So you know how different the
3 input was.

4 Q. You may have had more input into this
5 article than you did into Dr. Altman's study, his
6 article --

7 A. Uh-huh.

8 Q. -- but the fact remains that you and
9 others in Ethicon did have input into his article.
10 Correct?

11 MR. SNELL: Objection, form.

12 THE WITNESS: We made suggestions.

13 BY MR. SLATER:

14 Q. Now, let's look at this article by
15 Velemir, Amblard, Fatton, Savary and Jacquetin.

16 A. Uh-huh.

17 Q. This is an article that you believed
18 to be reliable and to have valid conclusions.
19 Correct?

20 A. As all literature or all studies,
21 they contribute to the total body of evidence on
22 this topic. And they all bring something.

23 Q. Let's look at the second page, which
24 is page 475.

25 Now, this study dealt with the

Confidential - Subject to Stipulation and Order of Confidentiality

1 Prolift®. Correct?

2 A. Yes.

3 Q. And it was a study of -- as titled,
4 "Transvaginal mesh repair of anterior and posterior
5 vaginal wall prolapse: a clinical and
6 ultrasonographic study." Correct?

7 A. Correct.

8 Q. Page 475, the first full paragraph in
9 the left column, the authors point out, "Between
10 2000 and 2005 our team participated in the
11 development of the tension-free vaginal mesh
12 technique. Over time it appeared that mesh
13 retraction was probably a contributing factor to

14 recurrence, postoperative pain and dyspareunia."

15 I read that correctly. Right?

16 A. Yes.

17 Q. And that was known to Ethicon before
18 the Prolift® was ever launched. Right?

19 A. Correct.

20 Q. This study, according to the methods
21 section just below there, involved the placement of
22 Prolifts® between 2005, March 2005 and August 2006.
23 Correct?

24 A. Correct.

25 Q. So this was from the launch of the

Confidential - Subject to Stipulation and Order of Confidentiality

1 Prolift® through about a little over a year later.

2 Right?

3 A. Yep.

4 Q. And these surgeons utilized the
5 Prolift® technique to place these Prolifts®.

6 Correct? Right?

7 A. Yes.

8 Q. Now, look at the next page, please,
9 page 476.

10 In the right-hand column they give
11 some of their statistics, and they point out that
12 nine of the patients, which is 9.9 percent, had
13 vaginal mesh exposure. Correct?

14 MR. SNELL: I'm sorry, where are you?

15 MR. SLATER: Right-hand column.

16 THE WITNESS: Here.

17 BY MR. SLATER:

18 Q. Correct?

19 A. Yes.

20 Q. They point out that at the one-year
21 follow-up, which they call the greater or equal to
22 one-year follow-up, 12, which was 13 percent, of the
23 patients presented with recurrence of vaginal wall
24 prolapse. Correct?

25 A. Yes.

Confidential - Subject to Stipulation and Order of Confidentiality

1 Q. Now, if we go a little further down,
2 the next paragraph, it talks about retraction of the
3 anterior mesh, which, if you add together moderate
4 and severe retraction, came to 89.3 percent.
5 Correct?

6 A. Retraction -- right. Uh-huh.

7 Q. And if you turn to the next page,
8 they group together the posterior mesh retractions,
9 and about 59 percent of the patients had retraction
10 of the posterior mesh. Correct?

11 A. How many did you say?

12 Q. It's at the top of the page. It's
13 48.4 percent plus 9.7 percent. Correct?

14 A. Yes.

15 Q. I rounded that to 59 percent.

16 Pretty close. Right?

17 A. Fine.

18 Q. So -- well, rephrase.

19 Those are extremely high rates of
20 retraction. Correct?

21 A. Yes.

22 Q. And these extremely high rates of
23 retraction were found where you had some of the most
24 experienced surgeons in the world with the Prolift®
25 technique placing the Prolift® in these patients.

Confidential - Subject to Stipulation and Order of Confidentiality

1 Correct?

2 A. That is correct.

3 Q. In the "Discussion," they talk

4 about -- well, rephrase.

5 In the "Discussion" they say in the

6 second sentence, "This study shows that mesh

7 retraction is associated with mesh thickening

8 measured on ultrasound." Okay. I want to stop

9 there.

10 That's something that Ethicon knew

11 even before the Prolift® was launched, that when

12 there's a mesh retraction, that the mesh is actually

13 thickened by the scar formation. Correct?

14 A. Right. So it's the composite of the

15 mesh and the scar. Yeah.

16 Q. It becomes like a single solid

17 substance. Correct?

18 A. Correct.

19 Q. And in this study, what the authors

20 did is they actually used ultrasounds to visualize

21 the mesh in vivo. Correct?

22 A. Uh-huh. Correct.

23 Q. And you certainly believe that is a

24 very valid technique to use where patients have

25 complications and you want to see what's happening